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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0218; FRL-9962-97]

Prosulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prosulfuron in or on grain, cereal, forage, fodder, and straw, group 16, stover; grain, cereal, forage, fodder, and straw, group 16, forage; grain, cereal, forage, fodder, and straw, group 16, hay; grain, cereal, forage, fodder, and straw, group 16, straw; and grain, cereal, group 15. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0218, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0218 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0218, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 19, 2016 (81 FR 31581) (FRL-9946-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F8455) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.481 be amended by establishing tolerances for residues of the herbicide prosulfuron, (*N*-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]-2-(3,3,3-

trifluoropropyl)benzenesulfonamide), in or on grain, cereal, forage, fodder, and straw, group 16, fodder at 0.01 parts per million (ppm); grain, cereal, forage, fodder, and straw, group 16, forage at 0.10 ppm; grain, cereal, forage, fodder, and straw, group 16, hay at 0.20 ppm; grain, cereal, forage, fodder, and straw, group 16, straw at 0.02 ppm; and grain, cereal, group 15 at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the commodity definition from grain, cereal, forage, fodder, and straw, group 16, fodder to grain, cereal, forage, fodder, and straw, group 16, stover. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for prosulfuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with prosulfuron follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The most prevalent effect observed across species and study durations following administration of prosulfuron was decreased body weight observed in subchronic and chronic oral toxicity studies in rats and dogs. Additionally, subchronic and chronic oral toxicity studies in dogs showed decreased hematological parameters and hepatic toxicity. Evidence of neurotoxicity was observed in an acute neurotoxicity study but not in the subchronic neurotoxicity study. The neurological effects seen in the acute neurotoxicity study were transient, affecting primary sensorimotor and gait functions. In a developmental range-finding study in rabbits, ataxia, hypoactivity, and neuropathology were observed starting at doses of 150 mg/kg/day. However, these potential signs of

neurotoxicity were not consistent with findings in the two main developmental studies in rabbits where there were no signs of neurotoxicity observed up to 200 mg/kg/day. Additionally, other repeated dosing studies in the rat, mouse, and dog did not show evidence of neurotoxicity. There is no evidence that prosulfuron is an immunotoxic chemical. Prosulfuron is classified as “*Not Likely to Be Carcinogenic to Humans*” based on the lack of evidence of carcinogenicity in mice and rats and no concern for mutagenicity. Prosulfuron has low acute toxicity by the oral, dermal, and inhalation routes of exposure, it is not considered an eye or skin irritant and it is not a skin sensitizer.

There was no evidence from the developmental and reproductive studies of increased susceptibility in rat or rabbit fetuses. In the first of two rabbit developmental studies, there were no signs of maternal or developmental toxicity. The second rabbit (tested using higher doses than the first) and the rat developmental studies showed dose-related increases in small fetuses and skeletal effects but these occurred at maternally toxic doses. In the reproductive study in rats, decreases in body weights were noted for both the adults of the P₀ and P₁ generations and for the F₁ and F₂ pups.

Specific information on the studies received and the nature of the adverse effects caused by prosulfuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document Prosulfuron. Human Health Risk Assessment in Support of a Section 3 Petition for the Expansion of Crop Groups 15 and 16 to Include Permanent Tolerances for Residues of Prosulfuron in Rice, pages 9-12 in docket ID number EPA-HQ-OPP-2016-0218.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-andassessing-pesticide-risks/assessing-human-health-risk-pesticides>

A summary of the toxicological endpoints for prosulfuron used for human risk assessment is shown in Table 1 of this unit.

Table 1. --Summary of Toxicological Doses and Endpoints for prosulfuron for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 years of age) (General population including infants and children)	NOAEL = 10 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Acute Neurotoxicity Study – Rat MRID 43387703 LOAEL = 250 mg/kg/day based on abnormal gait in females.
Chronic dietary (All populations)	NOAEL = 5.3 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.053 mg/kg/day cPAD = 0.053 mg/kg/day	Subchronic Oral Toxicity Study – Dog MRID 42685230 LOAEL = 54 mg/kg/day based on decreased feed efficiency, hematological findings and hepatotoxicity in both sexes.
Cancer (Oral, dermal, inhalation)	Prosulfuron is classified as “ <i>Not Likely to Be Carcinogenic to Humans</i> ” based on the lack of evidence of carcinogenicity in mice and rats and no concern for mutagenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to prosulfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing prosulfuron tolerances in 40 CFR 180.481. EPA assessed dietary exposures from prosulfuron in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for prosulfuron. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003-2008. As to residue levels in food, the acute dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM-FCID; version 3.18) and assumed 100 percent crop treated (PCT) and tolerance-level residues.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA NHANES/WWEIA conducted from 2003-2008. As to residue levels in food, the chronic dietary analysis was obtained from the DEEM-FCID; version 3.18 database and assumed 100 PCT and tolerance-level residues.

iii. *Cancer.* EPA has concluded that prosulfuron does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for prosulfuron. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for prosulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prosulfuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticidescience-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Tier 1 Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of prosulfuron for both acute exposures and chronic exposures for non-cancer assessments are estimated to be 37 parts per billion (ppb) for both surface water and ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration value of 37 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Prosulfuron is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found prosulfuron to share a common mechanism of toxicity with any other substances, and prosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that prosulfuron does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulativeassessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for prosulfuron includes a developmental toxicity study in the rat, two developmental toxicity studies and a range-finding developmental study in the rabbit, and a 2-generation reproduction toxicity study in the rat. There was no evidence of increased susceptibility of fetuses or offspring in any of these studies.

There were no maternal or fetal effects observed at any dose in the first of two rabbit developmental toxicity studies. In the second rabbit study and in the rat developmental toxicity study, a dose-related increase in small fetuses and skeletal effects was observed, but only in the presence of maternal toxicity (decreased body weight gain in the rat study; and increases in abortions, decreases in food consumption and decreased mean body weight gain in the rabbit study).

In the developmental range-finding study in rabbits, ataxia, hypoactivity, and neuropathology were observed starting at doses of 150 mg/kg/day. However, these potential signs of neurotoxicity were not consistent with findings in the two main developmental studies in rabbits where there were no signs of neurotoxicity observed up to 200 mg/kg/day. In the 2-generation reproduction study in the rat, decreases in body weight were observed in the F₁ and F₂ offspring but these occurred at doses in which parental toxicity was also observed. There was no evidence of neurotoxicity to fetuses or offspring observed in any of the developmental or reproduction toxicity studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the Food Quality Protection Act Safety Factor (FQPA SF) were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for prosulfuron is complete.
- ii. Although there was evidence of neurotoxicity in the acute neurotoxicity study and the range-finding developmental toxicity rabbit study, the selected endpoints are protective of these effects since they were seen at dose levels in excess of those where systemic toxicity occurred and at doses at least 15-fold higher than the no-observed adverse effect levels (NOAELs) selected for risk assessment. Concern is also low since no neurotoxicity was observed in the rest of the prosulfuron toxicological database, including the subchronic neurotoxicity study in rats.
- iii. As discussed in Unit III.D.2., there is no evidence that prosulfuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prosulfuron in drinking water. These assessments will not underestimate the exposure and risks posed by prosulfuron.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term

risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to prosulfuron will occupy 6.4 % of the aPAD for all infants (< 1 years old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to prosulfuron from food and water will utilize 3.9% of the cPAD for all infants (< 1 years old), the population group receiving the greatest exposure. There are no residential uses for prosulfuron.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, prosulfuron is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for prosulfuron.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, prosulfuron is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for prosulfuron.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, prosulfuron is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to prosulfuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, Method AG-590C (a high performance liquid chromatography method with column switching and ultraviolet (UV) detection), is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for prosulfuron.

C. Revisions to Petitioned-For Tolerances

EPA has revised the commodity definition from “grain, cereal, forage, fodder, and straw, group 16, fodder” to “grain, cereal, forage, fodder, and straw, group 16, stover” to

be consistent with the general food and feed commodity vocabulary EPA uses for tolerances and exemptions.

V. Conclusion

Therefore, tolerances are established for residues of prosulfuron, (*N*-[[4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]-2-(3,3,3-trifluoropropyl)benzenesulfonamide), including its metabolites and degradates, in or on grain, cereal, forage, fodder, and straw, group 16, stover at 0.01 ppm; grain, cereal, forage, fodder, and straw, group 16, forage at 0.10 ppm; grain, cereal, forage, fodder, and straw, group 16, hay at 0.20 ppm; grain, cereal, forage, fodder, and straw, group 16, straw at 0.02 ppm; and grain, cereal, group 15 at 0.01 ppm.

In addition, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of prosulfuron not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled

“Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 8, 2017.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.481, paragraph (a) is revised to read as follows:

§ 180.481 Prosulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of prosulfuron, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only prosulfuron (*N*-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]-2-(3,3,3-trifluoropropyl)benzenesulfonamide) in or on the commodity.

Commodity	Parts per million
Grain, cereal, forage, fodder, and straw, group 16, forage	0.10
Grain, cereal, forage, fodder, and straw, group 16, hay	0.20
Grain, cereal, forage, fodder, and straw, group 16, stover	0.01
Grain, cereal, forage, fodder, and straw, group 16, straw	0.02
Grain, cereal, group 15	0.01

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